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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

MYLAN PHARMACEUTICALS INC., *Plaintiff*, v. TEVA PHARMACEUTICALS INDUSTRIES LTD., TEVA PHARMACEUTICALS USA, INC., TEVA NEUROSCIENCE, INC., and TEVA SALES & MARKETING, INC., *Defendants*.	:	**Civil Action No. 2:21-cv-13087 (JXN/JSA)** **Oral Argument Requested** *Electronically Filed*

BRIEF IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS AND MOTION TO STRIKE

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page(s)

CASES:

STATUTES:

RULES AND REGULATIONS:

OTHER AUTHORITIES:

INTRODUCTION

Defendants Teva Pharmaceuticals Industries Ltd., Teva Pharmaceuticals USA, Inc., Teva Neuroscience, Inc., and Teva Sales & Marketing, Inc. (collectively, "Teva") developed Copaxone as an innovative therapy for patients suffering from relapsing forms of multiple sclerosis ("MS"), a disease that is the most common cause of neurological disability in young adults. *See* Complaint of Mylan Pharmaceuticals Inc. ("Compl.") ¶¶ 68-69. The active ingredient in Copaxone (glatiramer acetate, or "GA"), is exceptionally complex: as described by the Plaintiff, "Copaxone comprises an astronomical number of amino acid polymers with unique amino acid sequences that vary from batch-to-batch,"[1] and the way Copaxone works to treat MS is not fully understood.

Unsurprisingly, it took several years for companies seeking to market generic versions of GA to secure the necessary approvals from the U.S. Food and Drug Administration ("FDA"), since generic applicants faced the daunting task of proving that their products were "the same as" Copaxone. 21 U.S.C. § 355(j)(2)(A). Sandoz, Inc. first received approval in April 2015 to market a 20 mg version of generic GA. Compl. ¶¶ 75-76. Mylan lagged behind, but it ultimately received approval in October 2017 to market generic versions of GA in both 20 mg and 40 mg strengths. *Id.* ¶¶ 79-80. Since Mylan's 2017 launch,

[1] Mylan Cross-MSJ, at 3, No. 1:20-cv-00808, ECF No. 34-1 (D.D.C. July 2, 2020) (emphasis and footnote omitted).

competition has driven prices down for Copaxone/GA products by 47%-64%, with quarterly spending cut almost in half. *Id.* ¶ 218.

Yet Mylan is unsatisfied with the fruits of its competition and has turned to litigation. At bottom, Mylan's grievance is that Teva has competed hard and successfully against generic competitors; Mylan is unhappy because it "expected" to do better and for Teva to do worse. *See* Compl. ¶¶ 23, 112, 194, 196. But nothing required Teva to cede the marketplace to generic competitors without fighting back. Teva's challenged actions have been ***procompetitive*** and have benefitted consumers, exactly as the law allows and encourages. If Mylan ended up earning less than it had hoped as a result, this is just how competition works.

Mylan has filed what can only be described as a kitchen-sink Complaint against Teva. In doing so, Mylan ignores issues of timing: the Complaint challenges lawsuits and regulatory petitions filed by Teva more than a decade ago, even though such actions are outside the statute of limitations and have no bearing on Mylan's October 2017 FDA approval. *E.g.*, Compl. ¶ 102. Mylan also ignores geographic and jurisdictional boundaries: the Complaint devotes an entire section to allegations about regulatory activities in Europe, which are irrelevant to any cause of action asserted. *See id.* ¶¶ 92-100, 215. And perhaps most remarkably, Mylan discards any notion of intellectual consistency, labeling as anticompetitive Teva's efforts to compete by offering rebates even though Mylan has defended its

own materially indistinguishable rebate agreements for its branded EpiPen product as ***procompetitive***, industry-standard, and lawful. *See* p. 49, *infra*. As set forth below, Mylan does not state a plausible claim for relief, and its Complaint should be dismissed in full.

Sherman Act Section 2: The Complaint does not plausibly allege that Teva engaged in exclusionary conduct or that Mylan suffered antitrust injury, which dooms Mylan's Section 2 claim. Mylan advances two basic theories of antitrust harm: Teva engaged in conduct that (1) delayed Mylan's market entry, and (2) limited Mylan's market share once it entered. *E.g.*, Compl. ¶ 223.

Mylan's allegations fail to state a claim that Teva's conduct improperly delayed approval of Mylan's products. The Complaint relies on the illogical theory that lawsuits and regulatory petitions by Teva somehow continued to block the FDA from approving Mylan's GA products long after the lawsuits and petitions were resolved. Indeed, notwithstanding the ***same*** challenged lawsuits and petitions, Sandoz received approval to market the first generic GA product years before Mylan, which makes Mylan's causation theory unsupportable. Moreover, Mylan's delay allegations fail because they challenge petitioning activity that (1) is protected by the First Amendment and thus immune from antitrust attack, and (2) took place outside of the statute of limitations. Thus, the Court should dismiss any cause of action premised on the allegation that Teva was responsible for

delaying the approval and launch of Mylan's GA products.

Mylan's grievance that it failed to achieve greater market share post-approval also fails. The Complaint repeatedly mischaracterizes Teva's efforts to compete (*e.g.*, by entering rebate contracts and engaging in robust marketing) as antitrust violations. But stripped of conclusory labels, Mylan's allegations merely describe vigorous, legitimate competition by Teva. As Mylan itself has successfully urged, "it's perfectly lawful for a competitor to flex its economic muscle with vigor, imagination, devotion, and ingenuity, and act with sharp elbows—as businesses often do." *In re EpiPen (Epinephrine Injection, USP) Mktg., Sales Practices & Antitrust Litig.*, 507 F. Supp. 3d 1289, 1363 (D. Kan. 2020) (brackets and quotation marks omitted). While Mylan may have lost sales to Teva as a result, "[t]he antitrust laws are concerned with the protection of competition, not competitors." *Eisai, Inc. v. Sanofi Aventis U.S., LLC*, 821 F.3d 394, 399 (3d Cir. 2016) (quotation marks omitted). The Court should therefore also dismiss any claim premised on Teva's conduct occurring after Mylan's products were approved.

Lanham Act: The Complaint fails to state a claim under the Lanham Act for false advertising. That Act covers only alleged misrepresentations about competitors made in "commercial advertising or promotion," *see* 15 U.S.C. § 1125(a)(1)(B)—allegations of "isolated disparaging statements" are insufficient.

Fashion Boutique of Short Hills, Inc. v. Fendi USA, Inc., 314 F.3d 48, 57 (2d Cir. 2002). Yet here, the Complaint alleges facts about a handful of purported misrepresentations by Teva sales staff; Mylan's accusation that these misstatements were part of a broader disinformation campaign is pure speculation.

State-Law Claims: If the Court dismisses Mylan's federal claims, it should decline to exercise jurisdiction over the state-law claims.

FACTUAL BACKGROUND

I. Statutory Framework For FDA Drug Approval.

The Federal Food, Drug and Cosmetic Act governs the approval process to market both new and generic drugs. *See* 21 U.S.C. § 355(b), (j). Before a manufacturer can market a "new drug," it must submit a "new drug application" demonstrating that the drug is safe and effective for its intended use. *Id.* § 355(b)(1). The applicant also must identify any patents claiming the product or its intended use "for which a claim of patent infringement could reasonably be asserted." *Id.* § 355(b)(1)(A)(viii). Those listed patents are published in a database known as the Orange Book. *Id.* § 355(b)(1), (c)(2).

Applicants for generic drugs use an abbreviated pathway, which lets the manufacturer "piggyback[] on the safety-and-effectiveness information that the brand-name manufacturer[] submitted." *Celgene Corp. v. Teva Pharms. USA, Inc.*, 412 F. Supp. 2d 439, 441 (D.N.J. 2006) (quotation marks omitted). Such

applicants may submit an Abbreviated New Drug Application ("ANDA"), which must demonstrate that the proposed drug is "the same as" and "bioequivalent to" the brand drug. 21 U.S.C. § 355(j)(2)(A). A generic applicant that believes the patents claiming the brand product are either invalid or will not be infringed by the ANDA product must submit what is known as a "paragraph IV" certification. *Id.* § 355(j)(2)(A)(vii)(IV).

By statute, the submission of an ANDA with a paragraph IV certification constitutes an act of patent infringement, which lets the brand manufacturer file suit. *See* 35 U.S.C. § 271(e)(2). If the brand files suit within 45 days of receiving notice of the paragraph IV certification, the FDA is prohibited from granting final approval of the ANDA for a 30-month period. 21 U.S.C. § 355(j)(5)(B)(iii). But if the court in the patent case rules before 30 months that the patents on the brand drug are invalid or unenforceable, then the stay will expire early. *Id.* § 355(j)(5)(B)(iii)(I). This statutory 30-month stay on FDA ***approval*** does not prevent the FDA from ***reviewing*** an ANDA—the agency may grant the application "tentative approval" if it determines that an application is approvable but-for the stay. 21 C.F.R. §§ 314.105(d), 314.107(b)(3).

II. The Prescription Drug Market.

A number of entities are involved in getting approved prescription drugs to patients. *See* Compl. ¶ 65 (chart). Typically, manufacturers sell drugs to

wholesalers, who then sell the drugs to pharmacies. *Id.* The pharmacy is then reimbursed for the cost of the drug by the patient's health insurance provider. *Id.*

Pharmacy Benefit Managers ("PBMs") often operate in the middle of the distribution chain for prescription drugs, Compl. ¶ 62, "serv[ing] as intermediaries between pharmaceutical manufacturers and pharmacies on the one hand … and health benefit providers (e.g., insurers, self-insured entities, health maintenance organizations, and public and private health plans) on the other," *Pharm. Care Mgmt. Ass'n v. Rowe*, 429 F.3d 294, 298 (1st Cir. 2005). PBMs manage prescription drug benefits on behalf of health insurers, Medicare Part D drug plans, and other payors. Compl. ¶ 62. In this role, PBMs negotiate with drug manufacturers and pharmacies for rebates and discounts paid to the PBM's clients. *Id.* ¶¶ 62-63, 65 (chart).

PBMs also generate "formularies" for their payor-clients, which are lists of prescription drugs covered by the payor's healthcare plan. Compl. ¶ 64. If a prescribed drug is not on a PBM's formulary for a specific payor, the health plan generally will not cover the drug and the patient will be responsible for the full cost. *Id*. Consequently, drug manufacturers compete to have their drugs included on a PBM's formulary, including by offering the PBM higher rebates and discounts. *Id.* ¶ 66. The PBM market is highly concentrated, with the four largest PBMs accounting for approximately 75% of the market. *Id*. ¶ 67. This

"tremendous market power" gives PBMs considerable leverage in negotiations and allows PBMs "to demand concessions from the manufacturers," including "volume discounts and rebates." *Pharm. Care Mgmt. Ass'n*, 429 F.3d at 298; *see* Compl. ¶ 63 (similar).

State law also plays a role in determining which drug manufacturer's product is dispensed. Most states have enacted drug-selection laws, which generally either require or allow pharmacists to dispense a generic drug, even if the prescription identifies the brand drug. *See* Compl. ¶ 52. But states also typically authorize pharmacists to dispense the brand drug, even if a generic substitute is otherwise available, where the prescription lists the brand drug and specifies that it should be "dispensed as written." *Id.* ¶ 53.

III. Approval Of Copaxone And Mylan's Generic Products

A. The FDA Approves Copaxone 20 mg.

Copaxone is used to treat patients with relapsing forms of multiple sclerosis ("MS"). Compl. ¶ 68. Teva first received FDA approval to market Copaxone in December 1996, in 20 mg/vial form. *Id.* ¶ 73. In February 2002, the FDA approved Copaxone 20 mg to be administered through daily injections. *Id.* Unlike typical small-molecule drugs comprised of simple chemical compounds, Copaxone's active ingredient—glatiramer acetate ("GA")—is not a single molecular entity; it is composed of a heterogenous mixture of millions of distinct

synthetic polypeptides of varying lengths, sequences, and molecular weights. Mylan Cross-MSJ, at 1, 17, No. 1:20-cv-00808, ECF No. 34-1 (D.D.C. July 2, 2020). Due to these complexities, the drug's therapeutically active components have yet to be identified. *Id.*

B. Teva Submitted Citizen Petitions Requesting That The FDA Not Approve ANDAs For Copaxone.

In December 2007, several years after the FDA approved Copaxone 20 mg, another pharmaceutical company, Sandoz, submitted the first ANDA to market a generic version of GA 20 mg. Compl. ¶ 75. Teva promptly submitted a petition to the FDA—known as a "citizen petition"—requesting that the agency not approve generic versions of Copaxone. *Id.* ¶ 102; *see* Teva, Citizen Petition (Sept. 26, 2008) ("2008 Petition").[2] Teva's petition argued that the complexities of GA prevented a generic applicant from being able to "conclusively demonstrate that the clinically active polypeptide sequences in its purported generic product[s] are qualitatively and quantitatively the same as" Copaxone, as required to use the ANDA pathway. 2008 Petition, *supra*, at 2, 6, 7, 12 (quotation marks omitted).

[2] https://www.regulations.gov/document/FDA-2008-P-0529-0001. The Court can consider the citizen petitions and FDA's responses because they are referenced in Mylan's Complaint, Mylan's claims are based on the citizen petitions, and the petitions are part of the public record. *See Schmidt v. Skolas*, 770 F.3d 241, 249 (3d Cir. 2014) (holding that a court may take judicial notice of "matters of public record," such as regulatory filings, that are referenced in the complaint); *In re Restasis (Cyclosporine Ophthalmic Emulsion) Antitrust Litig.*, 333 F. Supp. 3d 135, 152 (E.D.N.Y. 2018) (taking judicial notice "of the contents of … three citizen petitions to the FDA" on a motion to dismiss).

By law, the FDA had to respond to a citizen petition within 180 days[3] of submission, 21 U.S.C. § 355(q)(1)(F) (2008), but the agency would deny a petition "without comment" if it sought a ruling affecting a "pending application," such as an ANDA, *see* FDA, *Citizen Petitions and Petitions for Stay of Action Subject to Section 505(q) of the Federal Food, Drug, and Cosmetic Act* 12-13 (June 2011).[4] At all relevant times, the FDA also was prohibited from "delay[ing] approval of a pending [ANDA] because of any request to take any form of action relating to the [ANDA]," and it was authorized to deny a petition that was "submitted with the primary purpose of delaying the approval of an application" and "d[id] not on its face raise valid scientific or regulatory issues." 21 U.S.C. § 355(q)(1)(A), (E) (2008).

Because applications to market generic GA products were pending, the FDA denied Teva's citizen petition without reaching the merits, concluding that it would be "premature and inappropriate" to "render a decision on a specific aspect of an ANDA … before [the FDA] … had an opportunity … to fully consider specific data and information in such an application." Dep't of Health & Human Servs., Letter Denying Citizen Petition, at 3 (Mar. 25, 2009) ("2009 Petition Denial").[5] In

[3] The time was later shortened to 150 days. *See* Pub. L. No. 112-114 § 1135, 126 Stat. 993, 1123 (July 9, 2012).

[4] https://www.regulations.gov/document/FDA-2009-D-0008-0011.

[5] https://www.regulations.gov/document/FDA-2008-P-0529-0007.

light of the FDA's approach, Teva was forced to resubmit several additional citizen petitions from 2009 to 2014, each time reprising its challenge to the approval of ANDAs referencing Copaxone while also addressing new scientific developments and data. Each time, the FDA denied the petition as premature. *See* Dep't of Health & Human Servs., Letter Denying Citizen Petition, at 1-3 (Apr. 16, 2015) ("Final Petition Denial").[6]

C. Mylan And Sandoz Submitted ANDAs On Copaxone 20 mg, Teva Sued Mylan And Sandoz For Patent Infringement, And The FDA Approved Sandoz's ANDA.

Sandoz's ANDA for 20 mg GA included a paragraph IV certification, Compl. ¶ 75, which prompted Teva to sue Sandoz for patent infringement, *see Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 876 F. Supp. 2d 295, 307 (S.D.N.Y. 2012). In June 2009, Mylan filed its own ANDA for 20 mg GA, which also included a paragraph IV certification. Compl. ¶ 78. Teva sued Mylan for infringement of seven patents covering Copaxone 20 mg in October 2009. *Teva Pharms. USA, Inc.*, 876 F. Supp. 2d at 308. Teva's lawsuits triggered statutory 30-month stays of FDA approval of the ANDAs, but those stays expired in January 2011 and March 2012, respectively. *See* 21 U.S.C. § 355(j)(5)(B)(iii)(I).

Teva prevailed substantially on its claims. In June 2012, the district court held that "both Mylan's and Sandoz's ANDA infringe[d] all of the asserted

[6] https://www.regulations.gov/document/FDA-2015-P-1050-0012.

claims" of the patents at issue, "and that none of [those] claims [was] invalid or unenforceable." *Teva Pharms. USA, Inc.*, 876 F. Supp. 2d at 419. The district court then enjoined Mylan and Sandoz from marketing a generic version of Copaxone 20 mg prior to the expiration of Teva's patents. *See* 1:08-cv-7611, ECF No. 338 (S.D.N.Y. July 24, 2012). The Federal Circuit affirmed in substantial part, holding that the ANDAs infringed all of the asserted patents, that Mylan and Sandoz had "failed to prove that [any of] the claims [were] obvious" or "not enabled," and that all asserted claims of three of the patents, as well as two of the three asserted claims of a fourth patent, were not indefinite. *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 723 F.3d 1363, 1366 n.2, 1375-76 (Fed. Cir. 2013).

The Federal Circuit did hold that a subset of claims was indefinite—including for a patent set to expire on September 1, 2015—and the district court modified its injunction to prohibit Mylan from marketing its generic product (if approved) only before May 24, 2014. *See* No. 1:08-cv-7611, ECF No. 355 (S.D.N.Y. Dec. 20, 2013). However, in January 2015, the Supreme Court vacated the Federal Circuit's judgment, holding that the Federal Circuit had applied the wrong standard of review to the district court's factual findings. *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 574 U.S. 318, 323-24, 336 (2015). While the case was pending in the Supreme Court, all but one of the asserted patents for Copaxone 20 mg expired. *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 789 F.3d 1335, 1338 n.3

(Fed. Cir. 2015). In June 2015, the Federal Circuit reiterated its conclusion that the remaining claims were indefinite, but did so in a 2-1 decision. *Id.* at 1345.

On April 16, 2015, the FDA approved Sandoz's ANDA. Compl. ¶ 75. That same day, the agency denied Teva's final citizen petition that had been filed a few weeks prior. *See* Final Petition Denial, *supra*, at 1-2, 43. In the 43-page decision, the FDA "recognize[d] that approval of ANDAs for glatiramer acetate injection raises complicated scientific and regulatory issues" given the "complexity of Copaxone." *Id*. at 3-4. Ultimately, the FDA disagreed with Teva's arguments, but it ***did not*** suggest that any of Teva's citizen petitions had been "submitted with the primary purpose of delay[]" or failed to "raise valid scientific or regulatory issues." 21 U.S.C. § 355(q)(1)(E) (2008).

D. The FDA Approves Copaxone 40 mg And Later Approves Mylan's ANDAs For 20 mg And 40 mg GA.

In 2013, Teva sought FDA approval to market Copaxone in a 40 mg dosage to be administered three times a week (rather than daily), which the FDA granted in January 2014. Compl. ¶ 74. This new dosage form allowed for a "more convenient" regimen for patients, since they would no longer have to endure daily injections. *Id.* ¶ 114. The FDA's approval, which was supported by new clinical studies submitted by Teva, triggered a three-year period of marketing exclusivity for Copaxone 40 mg, lasting until January 28, 2017. *Id.* ¶ 74; *see* 21 U.S.C. § 355(j)(5)(F). Teva began selling the new 40 mg product immediately, alongside

the 20 mg product. Compl. ¶ 118.

The following month, both Sandoz and Mylan filed ANDAs for 40 mg GA, prompting Teva to sue both for patent infringement, in September and October 2014, respectively. *See In re Copaxone Consolidated Cases*, 2017 WL 401943, at *8, *9 (D. Del. Jan. 30, 2017), *aff'd*, 906 F.3d 1013 (Fed. Cir. 2018). These lawsuits triggered statutory 30-month stays. Teva's three-year statutory exclusivity expired on January 28, 2017. Compl. ¶ 74. Two days later, on January 30, 2017, the district court in the 40 mg patent case held that the asserted claims were invalid as obvious. *In re Copaxone Consolidated Cases*, 2017 WL 401943, at *25. That decision ended the 30-month stay applicable to Sandoz's and Mylan's ANDAs for 40 mg GA. *See* 21 U.S.C. § 355(j)(5)(B)(iii)(I). Thus, as of January 2017, there was no exclusivity or litigation stay blocking the FDA from approving Mylan's 40 mg GA product. Even so, it was not until October 3, 2017—eight months after the stay had expired—that the FDA approved Mylan's 20 mg and 40 mg ANDAs. Compl. ¶ 79. Mylan then launched its generic versions of 20 mg and 40 mg GA. *Id.* ¶ 80.

E. Teva Competed With Mylan And Sandoz.

The Complaint alleges that Teva competed aggressively to maintain its market share following generic entry. For example, Mylan alleges that Teva engaged in a marketing campaign to convince medical professionals treating MS

patients to keep access to Copaxone and Teva's robust patient-support services (known as "Shared Solutions") by prescribing Copaxone "dispense as written" or "DAW." *E.g.*, Compl. ¶¶ 105, 131. The Complaint also alleges that Teva provided rebates to certain PBMs to place Copaxone 40 mg on their formularies, with some agreements allegedly conditioning rebates on exclusivity (*i.e.*, the exclusion of generic GA products from the formulary). *E.g.*, *id.* ¶¶ 101, 165. In addition, the Complaint alleges that Teva entered into an agreement with one or more PBM-owned specialty pharmacies to fill GA prescriptions with Copaxone at the pharmacy level in exchange for rebates or other discounts. *E.g.*, *id.* ¶ 166. Nevertheless, the Complaint admits that competition was effective in driving down prices, because "after generic entry for the 40mg dosage began in late 2017," prices for Copaxone and GA "decrease[d] by 47%-64%." *Id.* ¶ 218.

F. The FDA Denied Teva's Request To Reclassify Copaxone.

In 2019, after generic GA products had gained traction, the Complaint alleges that Teva tried to block Mylan from relying on state automatic substitution laws by seeking to reclassify Copaxone as a "biological product" under the Public Health Services Act, 42 U.S.C. § 262. Compl. ¶¶ 176-91. The FDA declined Teva's request, and Teva then filed suit against the FDA to challenge its decision. Compl. ¶¶ 182-83; *see Teva Pharms. USA, Inc. v. United States Food & Drug Admin.*, 514 F. Supp. 3d 66 (D.D.C. 2020). The district court ruled in favor of the

FDA in a 74-page published opinion. Compl. ¶¶ 188-90; *see Teva Pharms. USA, Inc.*, 514 F. Supp. 3d at 85, 117. The court agreed with Teva that the statute did not clearly favor the FDA's interpretation, but held that the statute was ambiguous and the FDA's interpretation was reasonable in light of the "complex scientific issues" involved. *Teva Pharms. USA, Inc.*, 514 F. Supp. 3d at 98-106.

LEGAL STANDARD

To survive a motion to dismiss, a complaint must allege "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). "[B]ald assertions" and "[l]egal conclusions masquerading as factual conclusions will not suffice." *Anspach ex rel. Anspach v. City of Phila., Dep't of Pub. Health*, 503 F.3d 256, 260 (3d Cir. 2007). Given "the unusually high cost of discovery in antitrust cases" that can "push cost-conscious defendants to settle even anemic cases," courts should apply pleading requirements rigorously to avoid the time and "potentially enormous expense" associated with litigating "largely groundless claim[s]." *Twombly*, 550 U.S. at 558-59 (citations omitted).

ARGUMENT

I. The Complaint Fails To Plausibly Allege A Section 2 Claim.

To state a claim for monopolization under Section 2, a plaintiff must allege: "(1) the possession of monopoly power in the relevant market and (2) the willful acquisition or maintenance of that power as distinguished from growth or development as a consequence of a superior product, business acumen, or historic

accident." *Mylan Pharms. Inc. v. Warner Chilcott Pub. Ltd. Co. ("Doryx")*, 838 F.3d 421, 433 (3d Cir. 2016). "A monopolist willfully acquires or maintains monopoly power when it competes on some basis other than the merits." *LePage's Inc. v. 3M*, 324 F.3d 141, 147 (3d Cir. 2003). Similarly, to allege a claim of "attempted monopolization" under Section 2, a plaintiff must allege: "(1) that the defendant has engaged in predatory or anticompetitive conduct with (2) a specific intent to monopolize and (3) a dangerous probability of achieving monopoly power." *Doryx*, 838 F.3d at 433.

An antitrust plaintiff also must plead an "antitrust injury," and "a causal link between the alleged injury and an antitrust violation's anticompetitive effects." *Phila. Taxi Ass'n, Inc v. Uber Techs., Inc.*, 886 F.3d 332, 343 (3d Cir. 2018). An "antitrust injury" is an injury "of the type the antitrust laws were intended to prevent"—*i.e.*, an injury that "flows from that which makes defendants' acts unlawful" and "reflect[s] the anticompetitive effect either of the violation or of anticompetitive acts made possible by the violation." *Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.*, 429 U.S. 477, 489 (1977).

"It is axiomatic that the antitrust laws were passed for the protection of competition, not competitors." *Brooke Grp. Ltd. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209, 224 (1993) (quotation marks and emphasis omitted). Thus, to plead a Section 2 claim, it is not enough to ask "whether the defendant has engaged

in unfair or predatory tactics." *Spectrum Sports, Inc. v. McQuillan*, 506 U.S. 447, 459 (1993) (quotation marks omitted). "Even an act of pure malice by one business competitor against another does not, without more, state a claim under the federal antitrust laws[.]" *Brooke Grp. Ltd.*, 509 U.S. at 225. Instead, an antitrust plaintiff must identify "conduct which unfairly tends to destroy competition itself." *Spectrum Sports, Inc.*, 506 U.S. at 458. These principles hold true in cases involving alleged monopolists. It "is in the interest of competition to permit dominant firms to engage in vigorous competition, including price competition," *Cargill, Inc. v. Monfort of Colorado, Inc.*, 479 U.S. 104, 116 (1986), as this is necessary "[t]o safeguard the incentive to innovate," *Verizon Commc'ns Inc. v. L. Offs. of Curtis V. Trinko, LLP*, 540 U.S. 398, 407 (2004). Thus, "the possession of monopoly power" is not a sufficient ground for antitrust liability, but must be accompanied by "an element of anticompetitive conduct." *Id.* (emphasis omitted).

Teva denies that it has monopoly power in a properly defined product market, or that there is a "dangerous probability" of it achieving monopoly power. But accepting those allegations for purposes of this motion, the Court should dismiss Mylan's Complaint because it fails to plausibly allege either anticompetitive conduct or antitrust injury as needed to sustain a Section 2 claim.

A. The Complaint Does Not Plausibly Allege That Any Action By Teva Delayed Approval Of Mylan's ANDAs.

Mylan begins by alleging that Teva engaged in a scheme to "delay[] generic entry through its repetitive and continuous abuse of the regulatory processes and court filings." Compl. ¶¶ 217, 238. The allegations Mylan offers to support this "delay" claim fail for three independent reasons. First, the Complaint does not include any factual allegations that plausibly link Teva's patent suits and regulatory filings to the fact that Mylan's two ANDAs did not receive FDA approval until October 2017. Compl. ¶¶ 78-79. Nor could it, as Sandoz received FDA approval for its generic product ***over two years before*** the FDA approved Mylan's product. Second, Teva's lawsuits and petitioning activity are protected by the First Amendment. Third, Mylan's "delay" claims are time barred.

1. Mylan Has Not Plausibly Alleged That Any Of Teva's Lawsuits Or Regulatory Filings Delayed Its Approval.

The Complaint offers conclusory allegations that Teva "delayed generic entry" through "abuse of the regulatory processes and court filings," Compl. ¶¶ 22, 217, but fails to explain ***how*** any regulatory or court filing actually impeded approval of Mylan's ANDAs. This omission is no accident: public records show there is no plausible connection between Teva's petitioning activity and Mylan's failure to secure approval until October 2017. This pleading omission mandates dismissal of any claim premised on delayed entry. *See In re Wellbutrin XL*

Antitrust Litig., 868 F.3d 132, 153 (3d Cir. 2017) (patent lawsuit against generic applicant "rightly rejected … as a basis of liability" absent evidence that the suit "actually delayed … entry"); *In re Remicade Antitrust Litig.*, 345 F. Supp. 3d 566, 581-82 (E.D. Pa. 2018) (similar).

a. Mylan Has Not Plausibly Alleged That Teva's Lawsuits Or Petitions Delayed Approval Of Mylan's 20 mg Product.

The timeline for Mylan's ANDAs shows that Teva's efforts to enforce its patent rights and to petition the FDA could not have caused the FDA to delay approval of Mylan's 20 mg ANDA until October 2017.

First, Teva's patent-infringement suit could not have impacted when the FDA approved Mylan's ANDA on GA 20 mg. By the October 2017 approval, there had been no litigation-based barrier to FDA approval for years: Teva sued Mylan in October 2009, the statutory 30-month stay expired in March 2012, and the FDA approved Mylan's ANDA ***five years*** later. *See* pp. 11-13, *supra*. Once the stay expired, the FDA was free to approve Mylan's ANDA, so long as Mylan had satisfied all applicable scientific and regulatory requirements.

Nor could the injunction entered by the court in the patent litigation have delayed approval of Mylan's 20 mg ANDA until October 2017. After ruling in Teva's favor, the district court enjoined the FDA from approving Mylan's 20 mg

ANDA, but only until September 1, 2015. *See* p. 12, *supra*.[7] That injunction was later modified to extend only until May 24, 2014. *See* p. 12, *supra*. Thus, after May 2014, the patent litigation posed no obstacle to FDA approval and could not have been the reason the FDA did not approve Mylan's ANDA for another three years. Indeed, Sandoz secured approval in April 2015, even though it was a defendant with Mylan in the same consolidated litigation. *See* Compl. ¶ 75.

Second, there is no plausible connection between Teva's citizen petitions and Mylan's approval date. As discussed, Teva filed its first petition in September 2008, just months after Sandoz filed its ANDA and before Mylan had filed its own. *See* pp. 9, 11, *supra*; Compl. ¶¶ 75, 78. Thus, far from strategically timing a citizen petition to hamper FDA review, Teva presented its concerns ***at the beginning of the review process***, leaving the FDA ample time to consider Teva's objections. The FDA's responses to Teva's petitions show that they caused no delay: the FDA denied Teva's first petition as "premature," explaining that the complex scientific questions Teva presented should be considered when reviewing a particular ANDA. 2009 Petition Denial, *supra*, at 3; *see* p. 10, *supra*. And the FDA denied Teva's refiled petitions on the same ground. *See* p. 11, *supra*. The FDA ultimately issued a substantive denial in April 2015, when it approved Sandoz's generic application. *See* p. 13, *supra*. Mylan offers no explanation as to

[7] That injunction is also legally irrelevant because Teva cannot be liable for harm to Mylan caused by Teva's ***victory on the merits*** in litigation. *See* p. 25, *infra*.

how those same regulatory filings could block its approval even though they did not block Sandoz.[8]

Mylan's theory of delay also contradicts controlling law. Federal law ***prohibits*** the FDA from delaying approval of an ANDA due to a pending citizen petition, unless delay "is necessary to protect the public health." 21 U.S.C. § 355(q)(1)(A). Tellingly, when Mylan was defending against antitrust claims in a different case, it correctly argued that the filing of citizen petitions "could not have caused delay as a matter of law" given the rules that now govern the process.[9] Moreover, the statute empowers the FDA to peremptorily deny petitions that are submitted for the purpose of delay and do not "raise valid scientific or regulatory issues." *Id*. § 355(q)(1)(E). Tellingly, the Complaint fails to allege that the FDA made such a determination here, because it did not.

b. Mylan Has Not Plausibly Alleged That Teva's Lawsuits Or Petitions Delayed Approval Of Mylan's 40 mg Product.

The Complaint likewise fails to plausibly allege that Teva's lawsuits or

[8] The FDA's approach reflected the agency's guidance on reviewing petitions that implicate a pending ANDA, as the agency "favors contemporaneous adjudications" of the petition and the ANDA "to safeguard the procedural rights of ANDA applicants." *Apotex Inc. v. Acorda Therapeutics, Inc.*, 823 F.3d 51, 60 (2d Cir. 2016); *see also* pp. 10-11, *supra*. The existence of this policy also "tends to undermine" any inference "that when a citizen petition is denied simultaneously with the grant of an ANDA petition, the citizen petition was a sham and an anticompetitive weapon." *Apotex, Inc.*, 823 F.3d at 60.

[9] Mylan MTD, at 29, No. 2:17-md-02785, ECF No. 95 (D. Kan. Dec. 15, 2017).

citizen petitions delayed approval of Mylan's 40 mg ANDA. As noted, Teva's final citizen petition was submitted and denied in 2015—it had no conceivable bearing on Mylan's October 2017 approval date. *See* p. 13, *supra*.

Nor could Teva's lawsuit about Mylan's 40 mg ANDA, and the resulting 30-month stay, have delayed FDA approval. Independent of the stay, Teva was entitled to three years of marketing exclusivity on Copaxone 40 mg, which barred the FDA from approving a generic 40 mg product until January 28, 2017. Compl. ¶ 74; *see also In re Wellbutrin*, 868 F.3d at 132 ("That a regulatory or legislative bar can break the chain of causation in an antitrust case is beyond fair dispute."). The 30-month litigation stay ended on January 30, 2017—just two days after the exclusivity period expired. *See* p. 14, *supra*. Yet the FDA did not approve Mylan's application for another ***eight months***, flatly contradicting any notion that the litigation stay impacted Mylan's approval. *See* Compl. ¶ 79.

2. Teva's Patent Suits And Citizen Petitions Are Immune From Antitrust Liability Under *Noerr-Pennington*.

Teva's patent suits and regulatory filings are also protected by the First Amendment and cannot support antitrust liability. "[T]hose who petition [the] government for redress are generally immune from antitrust liability." *Takeda Pharm. Co. Ltd. v. Zydus Pharms. (USA) Inc.*, 2021 WL 3144897, at *10 (D.N.J. July 26, 2021) (quoting *Prof'l Real Est. Invs., Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 56 (1993) ("*PRE*")). Under the *Noerr-Pennington* doctrine,

immunity is withheld only if the lawsuit (or other petition) is "a mere sham" to suppress competition. *PRE*, 508 U.S. at 56 (quotation marks omitted). "The sham … exception is narrow," *Takeda*, 2021 WL 3144897, at *11, as the plaintiff's claim must satisfy a two-part test. First, the lawsuit or petition "must be objectively baseless in the sense that no reasonable [party] could realistically expect success on the merits." *PRE*, 508 U.S. at 60. Second, the suit or petition must be intended to "use … the governmental process—as opposed to the outcome of that process—as an anticompetitive weapon." *Id*. at 60-61 (emphasis omitted).

Courts "may decide the applicability of the *Noerr–Pennington* doctrine on a motion to dismiss" when immunity does not depend on disputed facts. *Indivior Inc. v. Dr. Reddy's Lab'ys S.A.*, 2020 WL 4932547, at *8 (D.N.J. Aug. 24, 2020); *see also ADP, LLC v. Ultimate Software Grp., Inc.*, 2018 WL 1151713, at *3 n.3 (D.N.J. Mar. 5, 2018) (same). Because Mylan alleges no facts plausibly suggesting that Teva's lawsuits or citizens petitions were "objectively baseless," Mylan's claims attacking Teva's petitioning activity must be dismissed.[10]

[10] *See, e.g.*, *Duke Univ., Allergan, Inc. v. Akorn, Inc.*, 2019 WL 4410284, at *10 (D.N.J. Sept. 16, 2019); *Organon Inc. v. Mylan Pharms., Inc.*, 293 F. Supp. 2d 453, 462 (D.N.J. 2003); *Bristol-Myers Squibb Co. v. IVAX Corp.*, 77 F. Supp. 2d 606, 615, 620 (D.N.J. 2000); *see also Apotex Inc.*, 823 F.3d at 59-62; *Trustees of Univ. of Penn. v. St. Jude Children's Res. Hosp.*, 940 F. Supp. 2d 233, 242 (E.D. Pa. 2013).

a. The Complaint Does Not Plausibly Allege That Teva's Lawsuits Or Petitions Were "Objectively Baseless."

Plaintiffs face an uphill battle when alleging that a patent infringement suit under the Hatch-Waxman Act (like those at issue here) was a sham because "the submission of an ANDA is, by statutory definition, an infringing act." *In re Wellbutrin*, 868 F.3d at 149. Therefore, an infringement suit "filed in response to an ANDA with a paragraph IV certification could only be objectively baseless if no reasonable person could disagree with the assertions of noninfringement or invalidity in the certification." *Id*. The Complaint does not allege that any of Teva's patent suits meet this exceptionally demanding standard.

Beginning with the 20 mg litigation, Teva ***won*** in district court across-the-board, and the Federal Circuit ***affirmed*** the district court's judgment that all of the asserted patents were infringed and that numerous asserted claims were valid. *See* p. 12, *supra*. As to the remaining claims, the Federal Circuit agreed that the patents were enabled and non-obvious, but it concluded that those claims were indefinite. *See* p. 12, *supra*. Teva then successfully petitioned for certiorari, and the Supreme Court vacated the Federal Circuit's judgment. *See* p. 12, *supra*. Although the Federal Circuit reinstated its judgment of patent invalidity on remand, it did so over a dissent. This history dispels any notion that Teva's suit was "objectively baseless." Teva not only had a reasonable basis to believe "it had some chance of winning," *PRE*, 508 U.S. at 65—it ***did win*** much of its case.

Mylan fares no better as to Teva's infringement suit on the 40 mg ANDA. That case was vigorously litigated, resulting in a seven-day bench trial, a detailed district court opinion, and a published opinion from the Federal Circuit. *See* p. 14, *supra*. No court suggested that Teva's efforts to enforce its presumptively valid patents were objectively baseless. *See Tyco Healthcare Grp. LP v. Mut. Pharm. Co.*, 762 F.3d 1338, 1345 (Fed. Cir. 2014) ("[I]t will be a rare case in which a patentee's assertion of its patent in the face of a claim of invalidity will be so unreasonable as to support a claim that the patentee has engaged in sham litigation.").

Finally, the Complaint provides no basis to infer that any of Teva's regulatory filings with the FDA were "objectively baseless." The Complaint refers vaguely to supposed "abuse[] [of] the regulatory processes before the FDA," Compl. ¶¶ 102, 238, but does not identify any regulatory filings that were abusive. To the extent Mylan means to allege that Teva's citizen petitions were objectively baseless, the public record contradicts such an allegation. The FDA had statutory authority to dismiss Teva's citizen petitions outright if it believed they were objectively baseless. *See* 21 U.S.C. § 355(q)(1)(E). Rather than doing so, the FDA addressed the issues raised in Teva's citizen petitions in a 43-page decision, which acknowledged that the approval of generic GA products "raise[d] complicated scientific and regulatory issues," including challenges in establishing

"active ingredient sameness" given "the complexity of Copaxone." *See* Final Petition Denial, *supra*, at 3-4.

b. No "Serial" Petitioning Theory Is Viable Here.

Mylan also cannot avoid *Noerr-Pennington* immunity by invoking the so-called exception for "serial" petitioning involving repeat lawsuits or government petitions. In certain contexts, courts presented with a "pattern" of sham petitioning may go beyond the two-part test discussed above and consider whether "a series of petitions were filed with or without regard to merit and for the purpose of using the governmental process … to harm a market rival and restrain trade." *Hanover 3201 Realty LLC v. Vill. Supermarkets, Inc.*, 806 F.3d 162, 180 (3d Cir. 2015). This serial petitioning concept has no relevance here.

First, the Third Circuit has "declined to apply" a "serial petitioning" exception to *Noerr-Pennington* immunity "in the Hatch-Waxman context." *FTC v. AbbVie Inc.*, 976 F.3d 327, 361 (3d Cir. 2020). For good reason: the Hatch-Waxman Act deliberately incentivizes brand manufacturers to file patent suits against generic manufacturers seeking to enter the market, and it would be improper to "punish" brand manufacturers for "behavior that Congress sought to encourage." *Wellbutrin*, 868 F.3d at 158.

Second, the serial petitioning exception would not apply to Teva's citizen petitions, because the number of petitions filed is a byproduct of the FDA's

procedures. As discussed, the FDA's policy is to refrain from deciding issues raised in a citizen petition that are relevant to a pending ANDA, but the agency also must resolve a citizen petition within a set time period. *See* p. 10, *supra*. The FDA thus denied six Teva petitions as "premature," without reaching their merits (Teva withdrew another) and without delaying generic approval. *See* pp. 10-11, *supra*. For all practical purposes, Teva filed essentially one petition, which the FDA ruled on once.

3. Mylan's Challenge To Teva's Lawsuits And Citizen Petitions Is Barred By The Statute Of Limitations.

Mylan's allegation that Teva delayed FDA approval of Mylan's generic applications also must be dismissed as untimely because it relies on alleged conduct from outside the four-year statute of limitations period. *See* 15 U.S.C. § 15b. The limitations period "begins to run when a defendant commits an act that injures a plaintiff's business." *Zenith Radio Corp. v. Hazeltine Rsch., Inc.*, 401 U.S. 321, 338 (1971); *see also Berkey Photo, Inc. v. Eastman Kodak Co.*, 603 F.2d 263, 295 (2d Cir. 1979) (explaining that as to claims brought by a competitor, rather than by a consumer, the statute of limitations will accrue "at the time the anticompetitive conduct occurs"). In particular, "sham" petitioning claims accrue when the relevant petition (or lawsuit) is filed. *See, e.g.*, *AL George, Inc. v. Envirotech Corp.*, 939 F.2d 1271, 1275 (5th Cir. 1991); *Pace Indus., Inc. v. Three Phoenix Co.*, 813 F.2d 234, 238-39 (9th Cir. 1987).

This lawsuit was filed on June 29, 2021, so any claim that accrued on or before June 29, 2017 is time barred. By June 2017, Teva's patent suit on the 20 mg product—which was filed in 2009—had been over for years. *See* pp. 11-13, *supra*. Likewise, Teva filed its final citizen petition (and the FDA denied that petition) more than two years before the June 2017 accrual date. *See* p. 13, *supra*. Finally, Teva's patent litigation on the 40 mg product was filed in October 2014—over two years before the June 2017 accrual date—and the district court decision resolving that case was issued several months before the accrual date. *See* p. 14, *supra*. Thus, Mylan cannot seek damages for any injury allegedly caused by Teva's pre-approval lawsuits or petitioning activity.

B. The Complaint's "Product Hopping" Allegations Are Fundamentally Flawed And Cannot Support A Claim For Relief.

Mylan next accuses Teva of "shifting" the market to Copaxone 40 mg to stifle generic competition, an alleged practice sometimes referred to as "product hopping." Compl. ¶¶ 112-30. But Mylan's theory suffers from two fundamental flaws. First, the Complaint fails to plausibly allege that Teva engaged in improper coercion. Teva never withdrew its 20 mg product from the market, meaning "the free choice of consumers" has always been "conserved." *In re Asacol Antitrust Litig.*, 233 F. Supp. 3d 247, 269 (D. Mass. 2017). Second, the Complaint does not plausibly allege that any market-shifting efforts caused Mylan to suffer antitrust injury: Mylan did not have approval to market a 20 mg GA product during the

relevant period, and thus could not have been injured by alleged efforts to shift patients away from 20 mg Copaxone to the new 40 mg formulation.

1. Teva's Efforts To Introduce And Promote Copaxone 40 mg Were Not Anticompetitive.

Teva's alleged efforts to shift the market to its new 40 mg product were not anticompetitive as a matter of law. "[C]ourts are properly very skeptical about claims that competition has been harmed by a dominant firm's product design changes." *United States v. Microsoft Corp.*, 253 F.3d 34, 65 (D.C. Cir. 2001) (en banc). The case law is "clear … that simply introducing a new product on the market, whether it is a superior product or not, does not, by itself, constitute exclusionary conduct." *In re Suboxone (Buprenorphine Hydrocholoride & Naloxone) Antitrust Litig.*, 64 F. Supp. 3d 665, 682 (E.D. Pa. 2014).

Here, Mylan acknowledges that Copaxone 40 mg represented an advance over Copaxone 20 mg—it allows for "a less frequent and more convenient regimen" because patients need only three injections per week rather than daily injections. Compl. ¶ 114. And because "[p]roduct innovation generally benefits consumers and inflicts harm on competitors," courts seek to "distinguish between conduct that defeats a competitor because of efficiency and consumer satisfaction and conduct that impedes competition through means other than competition on the merits." *New York ex rel. Schneiderman v. Actavis PLC ("Namenda")*, 787 F.3d 638, 652 (2d Cir. 2015). Only in the latter scenario, where improper "coercion" by

a monopolist blocks consumer choice, is the conduct potentially actionable under Section 2. *Doryx*, 838 F.3d at 440-41. The Complaint fails to allege any such coercion resulting from Teva's introduction of Copaxone 40 mg.

a. Mylan Does Not Allege A "Hard Switch."

As a threshold matter, Mylan cannot state a Section 2 claim based on Teva's alleged market-shifting strategy because it does not allege that Teva engaged in a "hard switch." In adjudicating claims involving an alleged "product hop" by a brand to a new patent-protected product, courts have drawn "an important distinction between hard and soft switches." *In re Asacol*, 233 F. Supp. 3d at 269. In a "hard switch," the brand withdraws its old product from the market before generic entry to "force[] patients" to shift to a new patent-protected formulation. *Namenda*, 787 F.3d at 654. Some courts have held that a hard switch may "cross[] the line from persuasion to coercion." *Id*. By contrast, in a "soft switch," the brand tries "to persuade patients and their doctors to switch" from the old formulation to a new one "while both [are] on the market." *Id*. A soft switch does "not have the same anticompetitive result," and is not actionable under Section 2, because "the market" remains able to "determine whether one product is superior to another … so long as the free choice of consumers is preserved." *In re Asacol*, 233 F. Supp. 3d at 269 (alteration in original and quotation marks omitted).

The Complaint does not allege that Teva executed a "hard switch" when it

launched Copaxone 40 mg. To the contrary, it recognizes that Copaxone 20 mg "remained on the market throughout th[e] period" of Teva's alleged shift. *In re Asacol*, 233 F. Supp. 3d at 268; *see* Compl. ¶¶ 129, 175. Indeed, Copaxone 20 mg remains available ***to this day***.[11] Because Teva always "maintained both products on the market, [it] did not interfere with [Mylan's] freedom to compete … ***as a matter of law***." *In re Asacol*, 233 F. Supp. 3d at 269 (emphasis added).

Courts have consistently dismissed Section 2 claims, like this one, that do not allege a "hard shift." *See, e.g.*, *id.*; *In re Solodyn (Minocycline Hydrochloride) Antitrust Litig.*, 2015 WL 5458570, at *13 (D. Mass. Sept. 16, 2015) (dismissing Section 2 claim premised on brand's alleged efforts "to shift the market away from doses" of Solodyn "that stood to face generic competition" toward "new strengths" because the brand "continued selling the [le]gacy [s]trengths" for several years); *Walgreen Co. v. AstraZeneca Pharms., L.P.*, 534 F. Supp. 2d 146, 148, 151-52 (D.D.C. 2008) (dismissing Section 2 claim premised on allegations that AstraZeneca "deliberately switched the market" from Prilosec to Nexium "just as Prilosec's patent was about to expire" because AstraZeneca kept both products on the market and therefore had not "eliminat[ed] choices available to the

[11] www.copaxone.com/about-copaxone/dosage-information (accessed Nov. 19, 2021).

consumer").[12] This Court should reach the same result.

b. The Complaint Does Not Plausibly Allege Coercion Absent A "Hard Shift."

Unable to allege the hard switch that courts have found essential to stating a Section 2 claim, Mylan nonetheless insists that Teva's efforts to shift the market were improperly coercive. Compl. ¶¶ 119-30. But its allegations fail to plausibly allege that Teva engaged in anticompetitive conduct.

First, the Complaint alleges that Teva made the price of Copaxone 40 mg too attractive by setting "the launch price for Copaxone 40mg lower than the weekly price of Copaxone 20mg." Compl. ¶ 120. According to Mylan, it was "economically irrational" for Teva "to charge less for the allegedly better product." *Id*. But there is nothing irrational, or even particularly unusual, about a company seeking to win consumers over to a new product with discounts. *See* Robert Reich, *Toward a New Consumer Protection*, 128 Penn. L. Rev. 1, 22 (1979) ("It is often necessary for sellers to offer new products at a discount … in order to offset consumers' understandable reluctance to sail such uncharted seas.").

In any event, Mylan cannot support a Section 2 claim by alleging that the introductory price for Copaxone 40 mg was ***too low***. "Low prices benefit

[12] Conversely, courts that have let product-hopping theories move forward have invariably relied on a hard shift. *See, e.g.*, *Namenda*, 787 F.3d at 654; *In re Loestrin 24 Fe Antitrust Litig.*, 261 F. Supp. 3d 307, 353 (D. R.I. 2017); *In re Suboxone*, 64 F. Supp. 3d at 681.

consumers regardless of how those prices are set, and so long as they are above predatory levels"—as the prices here indisputably were—"they do not threaten competition." *Atl. Richfield Co. v. USA Petroleum Co.*, 495 U.S. 328, 340 (1990). "The antitrust laws condemn high prices, not low ones," making "it wholly inappropriate to use the Sherman Act to oblige [a defendant] to raise its price[s]." *Schor v. Abbott Labs.*, 457 F.3d 608, 610-11 (7th Cir. 2006).

The Complaint also alleges that Teva took steps to induce price separation by increasing the price of Copaxone 20 mg, but it relies primarily on actions that Teva allegedly considered but did ***not*** take. Compl. ¶¶ 121-22. All that is left is the bare allegation that Teva increased the price of Copaxone 20 mg "by 9.8% in August 2014." *Id*. ¶ 121. The Complaint does not allege any facts to infer this price increase was out-of-line with standard adjustments for both the 20 mg and 40 mg products, *id*. ¶ 72, or otherwise provide a basis for inferring coercion.

Second, Mylan objects to Teva's efforts to promote access to Copaxone 40 mg by allegedly "condition[ing] contractual rebates for Copaxone 20mg on the addition of Copaxone 40mg to the PBMs' formularies." Compl. ¶ 123. Mylan labels this negotiating position a "tying tactic," *id*. ¶ 124, but the Complaint does not allege improper "tying" within the meaning of antitrust law. "[A] tying arrangement may be defined as an agreement by a party to sell one product … but only on the condition that the buyer also purchases a different (or tied) product …,

or at least agrees that he will not purchase that product [or service] from any other supplier." *Avaya Inc., RP v. Telecom Labs, Inc.*, 838 F.3d 354, 397 (3d Cir. 2016). Here, the Complaint does not allege that Teva ***required*** customers to purchase Copaxone 40 mg in order to maintain access to Copaxone 20 mg. It does not even allege that Teva required minimum purchase commitments for Copaxone 40 mg or demanded exclusivity. Rather, Teva simply required that PBMs seeking discounts for one Teva product agree to provide coverage for a second Teva product. The mere "threat of a lost discount is a far cry" from the kind of anticompetitive conduct courts have found unduly coercive. *Eisai, Inc.*, 821 F.3d at 407.

Resisting that conclusion, the Complaint implausibly characterizes Teva's rebate condition as "remov[ing] … choice from purchasers," Compl. ¶ 123, but the opposite is true. Teva's contractual requirement helped to provide consumers with ***more*** choice: they could stick with Copaxone 20 mg or switch to the "more convenient regimen" provided by the new product. *Id*. ¶ 114. Even assuming that this made it more difficult for PBMs to steer doctors and patients away from Copaxone 40 mg, *id*. ¶ 123, there is no principle of antitrust law that prioritizes maximizing the leverage of PBMs over consumer access to new medicines.

Finally, the Complaint alleges that Teva sought to convert Copaxone prescriptions through its own marketing efforts, and by contracting with PBMs and insurers to encourage doctors and patients to make a switch. Compl. ¶¶ 125-27.

But it is not coercive for Teva to have persuaded doctors and patients to switch to the "more convenient regimen" offered by Copaxone 40 mg. *Id.* ¶ 114. Nothing in "antitrust law … prohibits market switching through sales persuasion short of false representations or fraud,"[13] and Teva is aware of no "court that has identified such conduct as exclusionary for purposes of § 2 of the Sherman Act." *Walgreen Co.*, 534 F. Supp. 2d at 152. This Court should not be the first.

2. Mylan Does Not Plausibly Allege That It Was Injured By A Shift From Copaxone 20 mg To Copaxone 40 mg.

According to the Complaint, once the FDA approved Teva's 40 mg product, Teva took steps to "rapidly and significantly shift[] the market from the 20mg product to the 40mg product just in time to blunt the effect of generic competition," which commenced "when the FDA approved 20mg GA" in April 2015. Compl. ¶¶ 128, 218. But the FDA did not approve Mylan's 20 mg until October 2017, and it approved Mylan's 40 mg product on the same day. Compl. ¶ 79. Thus, when Mylan launched, it competed as to ***both*** the 20 mg and 40 mg strengths. There was no period in which Mylan was on the market with only a 20 mg product, and thus no plausible way it could have been injured by Teva's alleged efforts to promote the 40 mg formulation.

[13] The Complaint alleges that Teva made misstatements about Mylan's generic product. For the reasons discussed below, those allegations do not support a Sherman Act claim. *See* Part I.C, *infra*. But as relevant here, there are no allegations that Teva made any false representations in connection with its efforts to shift patients and doctors from Copaxone 20 mg to Copaxone 40 mg.

The Complaint does not try to connect its "market shift" theory to an alleged Mylan injury. *See* Compl. ¶¶ 192-203 (describing how Teva's conduct allegedly "harms Mylan" without referencing the product-hopping theory). That omission dooms Mylan's claim, because there must be a "causal link between the alleged injury and an antitrust violation's anticompetitive effects." *Phila. Taxi Ass'n*, 886 F.3d at 343; *see also Doryx*, 838 F.3d at 439-40 (rejecting claim premised on "product hopping" where Mylan failed to show it had been "harmed by Defendants' product changes").[14] Moreover, if Mylan were to allege it was somehow harmed by Teva's alleged market-shifting actions in 2014-2015, before Mylan secured FDA approval, then its claim would be barred by the four-year statute of limitations. *See* pp. 28-29, *supra*.

C. Teva's Efforts To Compete Against Mylan's Generic Product Do Not Support A Claim Under The Sherman Act.

Unable to plausibly allege that any actions taken by Teva before Mylan entered the market were anticompetitive or caused Mylan to suffer injury, the Complaint turns to challenge Teva's efforts to compete once Mylan's products became available. Compl. ¶¶ 131-91. None of the allegations supports a Section 2

[14] To the extent Mylan intends to argue that Teva's alleged market-shift strategy should be considered as background evidence of an anticompetitive "scheme," Compl. ¶ 216, its position is legally baseless: a private plaintiff "may not challenge" conduct if it "has failed to allege that it sustained an antitrust injury as a result of [that conduct]." *W. Penn Allegheny Health Sys., Inc. v. UPMC*, 627 F.3d 85, 110 n.16 (3d Cir. 2010).

claim, either independently or collectively. To the contrary, Mylan's grievance appears to be that Teva competed vigorously to maintain its market share after generic entry. Such competition is exactly what the antitrust laws ***encourage***.

1. Teva's "Dispense As Written" Campaign Was Not Anticompetitive.

Mylan first alleges that Teva engaged in anticompetitive conduct by undertaking a "dispense as written" campaign, during which members of the Teva salesforce allegedly made statements to disparage Mylan's product. *See* Compl. ¶¶ 13, 131-59. An antitrust claim premised on allegedly false advertising faces a steep uphill climb. Advertising, even if "false or misleading," "generally sets competition into motion" by providing a rival with a chance to counter, *Retractable Techs., Inc. v. Becton Dickinson & Co.*, 842 F.3d 883, 895 (5th Cir. 2016); *see also Mercatus Grp., LLC v. Lake Forest Hosp.*, 641 F.3d 834, 851 (7th Cir. 2011) ("[E]ven false statements about a competitor serve to set the stage for competition." (quotation marks omitted)). Numerous courts have thus endorsed "a presumption that misrepresentations or false statements about a competitor have a *de minimis* effect on competition," and therefore "do not give rise to a federal antitrust claim." *Duty Free Ams., Inc. v. Estee Lauder Cos., Inc.*, 797 F.3d 1248, 1268 (11th Cir. 2015) (collecting decisions). The Third Circuit has likewise made clear that false or deceptive statements about a competitor do not give rise to antitrust liability, except in "rare[ ] circumstances." *Eisai, Inc.*, 821 F.3d at 407-08

n.40. At a minimum, the plaintiff must plausibly allege that "false or deceptive statements … induced or were likely to induce reasonable reliance by consumers," which the plaintiff "could not have corrected" with counter-advertising. *Id.*

Mylan's claim falls far short under these standards. The Complaint relies heavily on a handful of alleged instances in which a few unnamed medical professionals expressed concerns about switching from Copaxone, some "portion" of whom allegedly attributed disparaging statements about Mylan's product and services to Teva sales representatives. *See* Compl. ¶¶ 138, 144-45, 149-50, 156. The Complaint does not identify whether the alleged statements came before or after Mylan secured FDA approval, despite Mylan's allegation that Teva's statements were contradicted by the FDA's approval decision and Mylan's press release announcing that decision. *See id.* ¶¶ 137, 146, 151. The Complaint also alleges instances in which medical professionals "expressed a reluctance to allow their MS patients to be switched to Mylan's GA product," but it does not connect their reluctance to any specific false or misleading statement attributed to Teva. *Id.* ¶ 153; *see also id.* ¶¶ 143, 148, 155, 157.

From those vague allegations, the Complaint jumps to the conclusion that the scattered statements it identified "reflect[] a coordinated campaign by Teva to spread misinformation about Mylan's GA product," which was responsible for "persuad[ing] a large number of doctors to write DAW prescriptions for Copaxone

and patients to request them." Comp. ¶¶ 158, 160. But the Complaint's leap is not plausible in light of an "obvious alternative explanation" for brand loyalty. *Twombly*, 550 U.S. at 567-68. As Mylan has acknowledged, GA is exceptionally complex and difficult to reproduce. *See* pp. 8-9, *supra*. Moreover, taking a dose of Copaxone is not like swallowing a pill—it involves a precise injection protocol that requires active patient support and training. *See* Compl. ¶ 151. Given doctors' and patients' decades-long experience with Copaxone, it is unremarkable that many doctors and patients would have been reluctant to alter a treatment regimen that had been working. There is thus no basis to infer that Teva engaged in a vast disinformation campaign following Mylan's generic approval based merely on the alleged success of Teva's marketing efforts and allegations that a handful of health providers in a handful of states attributed purported misrepresentations to Teva.

The implausibility of Mylan's theory is compounded by the nature of the audience allegedly targeted by the supposed disinformation campaign. False advertising may induce reasonable reliance when statements are "made to buyers without knowledge of the subject matter," *Am. Prof'l Testing Serv., Inc. v. Harcourt Brace Jovanovich Legal & Prof'l Publ'ns, Inc.*, 108 F.3d 1147, 1152 (9th Cir. 1997), but those are not the facts alleged here. The medical professionals targeted by Teva's alleged dispense-as-written campaign were "sufficiently sophisticated so as not to be fooled easily by … misinformation," *Tate v. Pac. Gas*

& Elec. Co., 230 F. Supp. 2d 1072, 1080 (N.D. Cal. 2002); *see also Retractable Techs.*, 842 F.3d at 895 (reliance on false statements less likely "where, as here, the relevant consumers are sophisticated"). The Complaint provides no plausible reason to conclude that "medical professionals who treat MS patients" would blindly defer to Teva's characterizations of a rival's product and services, Compl. ¶ 131—much less that a "large number of doctors" would do so, *id*. ¶ 160.

Finally, and relatedly, the Complaint fails to plausibly allege that Mylan could not "correct[]" Teva's alleged "misstatements" by providing medical professionals "with accurate information" about Mylan's product and services. *Eisai, Inc.*, 821 F.3d at 407-08 n.40. This dooms Mylan's allegations because "[t]here can be no harm to competition … when the victims of false advertising are easily able to counter it." *Am. Council of Certified Podiatric Physicians & Surgeons v. Am. Bd. of Podiatric Surgery, Inc.*, 323 F.3d 366, 372 (6th Cir. 2003). The Complaint does allege in conclusory fashion that "Mylan endeavored to correct" the alleged misrepresentations with "very limited impact," Compl. ¶ 162, but the relevant legal question is whether Teva's alleged misstatements were "susceptible to neutralization," not whether Mylan's marketing efforts were "successful." *Am. Prof'l Testing Serv.*, 108 F.3d at 1152.

Ultimately, Mylan seems to dismiss counter-speech as a solution because it objects to spending any resources on marketing a generic drug, Compl. ¶ 199, and

views the very concept of a "dispense as written" campaign as an illegitimate effort by a brand to "undermine" the "automatic substitution laws," *id.* ¶¶ 133-34. But advocating for medical providers to write "dispense as written" is simply one way that brand manufacturers ***compete*** in light of those laws. There is nothing illegitimate or anticompetitive about a brand reminding medical providers or patients how to preserve access to the brand product, within the regulatory framework of state drug-selection laws, if they want to do so.

2. Teva's Alleged Rebate Agreements With PBMs And Specialty Pharmacies Did Not Harm Competition.

The Complaint next accuses Teva of entering into agreements with PBMs and PBM-owned specialty pharmacies "to exclude generic GA from formularies and dispensing." Compl. ¶¶ 106-07, 163-75. But stripped of its pejorative labels and conclusory allegations, the Complaint describes entirely legitimate price competition by Teva in response to generic entry, which plainly cannot support a Section 2 claim. Teva's decision to compete against Mylan (and Sandoz) by lowering its prices to make its product more attractive to customers and to retain sales is exactly the kind of procompetitive conduct that antitrust law ***encourages***.

The Complaint challenges two types of contractual arrangements between Teva and unidentified PBMs:

- **Conditional PBM Rebates.** Agreements between Teva and some PBMs in which Teva allegedly "conditioned the payment of rebates" and, "on information and belief," unspecified other "payments and/or

inducements," on the PBMs' agreement to cover Copaxone on their formularies while excluding generic GA. Compl. ¶ 165.

- **Specialty Pharmacy Agreements.** Agreements between Teva and some PBM-owned specialty pharmacies that "incentivized" the pharmacies to fill prescriptions for GA products with branded Copaxone, even though the pharmacies could have filled those prescriptions with generic products under state substitution laws. Compl. ¶ 166.

The Complaint baldly asserts that these agreements "went beyond ordinary competition." Compl. ¶ 106. Even if true, that would not support an antitrust claim—the Sherman Act does not bar innovative efforts to compete that are "unique in the industry." *FTC v. Qualcomm Inc.*, 969 F.3d 974, 1001-03 (9th Cir. 2020). Regardless, the Complaint fails to identify anticompetitive action by Teva; instead, it recounts on-the-merits competition by Teva to win market share by providing PBMs and specialty pharmacies with the most attractive terms—procompetitive conduct that ultimately benefits patients through lower prices and more efficient services. *See* pp. 47-48, *infra*. As a result, the Complaint does not plausibly allege that these agreements were anticompetitive or that they caused Mylan to suffer antitrust injury.

a. Mylan's Claims Challenging Teva's Rebate Contracts With PBMs And Specialty Pharmacies Are Subject To The Price-Cost Test, Which Mylan Cannot Satisfy.

Mylan's allegations regarding the PBM and specialty pharmacy contracts amount to objections to Teva's use of price incentives to compete. According to the Complaint, Teva used "rebates" and other unspecified financial "inducements"

to win business for Copaxone, leading certain specialty pharmacies to fill prescriptions for GA with Copaxone, rather than a generic product, and leading an unspecified number of PBMs to include Copaxone on their formularies while excluding generic GA. Compl. ¶¶ 165-66. Even if true, those allegations fail to describe anticompetitive or exclusionary conduct.

"[C]utting prices in order to increase business often is the very essence of competition." *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 594 (1986). Courts are thus deeply skeptical of antitrust challenges to discounts and rebates, because such challenges risk "chill[ing] the very conduct the antitrust laws are designed to protect." *Id*. Reflecting this skepticism, courts in the Third Circuit apply the "price-cost test" where, as here, the plaintiff alleges that price is a rival's "clearly predominant mechanism of exclusion." *ZF Meritor, LLC v. Eaton Corp.*, 696 F.3d 254, 275 (3d Cir. 2012). Under that test, a plaintiff's challenge to a defendant's rebates fails if the defendant's prices remain "above-cost." *Eisai, Inc.*, 821 F.3d at 409. Here, the Complaint alleges that Copaxone prices remained above "Teva's marginal cost," Compl. ¶ 208, which sinks Mylan's claim.

Importantly, the price-cost test controls "regardless of the way in which the plaintiff casts its grievance"—whether as an objection to bundling, or exclusive dealing, or using rebates to obtain preferred formulary position, or anything else; all that matters is that "pricing itself" is alleged to have "operated as the

exclusionary tool." *ZF Meritor, LLC*, 696 F.3d at 275. And it plainly applies in cases involving the conditional rebates and pricing incentives alleged here. Indeed, Mylan itself has argued that challenges to "conditional rebates" to "obtain a preferred formulary position"—including rebates for "exclusivity"—should be evaluated under the price-cost test. *See* Mylan MSJ, at 2, 56-57, No. 17-md-2785, ECF No. 1673-1 (D. Kan. June 28, 2019).[15] In litigation involving EpiPen, Mylan explained that "formulary exclusion" is "common in the industry," and argued that the use of above-cost rebates or other discounts to secure exclusivity or other preferred formulary status is *per se* lawful under the price-cost test. *Id.* That position aligns with precedent recognizing that "pricing will predominate[] over other means of exclusivity" when, for example, a company offers a "rebate to compete with similar products." *Eisai, Inc.*, 821 F.3d at 409.

There is no basis for Mylan to avoid the price-cost test here. As to the Specialty Pharmacy Agreements, price is not merely alleged to be the "predominant mechanism of exclusion," *ZF Meritor, LLC*, 696 F.3d at 269; it is Mylan's ***only*** alleged theory of exclusion. The Complaint alleges that "Teva paid the PBM-owned specialty pharmacies" to fill prescriptions with branded

[15] *See also* Mylan MTD, at 40 & n.27, No. 20-cv-827, ECF No. 92 (D. Minn. Aug. 21, 2020) ("Plaintiffs allege that Mylan offered rebates and discounts to PBMs in exchange for preferred position on PBM formularies. … Because price discounts to customers are ***procompetitive***, not anticompetitive, Plaintiffs' allegations cannot satisfy their burden of alleging anticompetitive conduct[.]").

Copaxone—*i.e.*, Teva paid the PBM "an additional rebate" to encourage the dispensing of Copaxone rather than generic GA. Compl. ¶¶ 166-67 (quotation marks omitted). The Complaint does not allege any facts to suggest that Mylan could not have tried to "match" Teva's rebates to induce specialty pharmacies to dispense its product instead. *Eisai, Inc.*, 821 F.3d at 409. As Mylan put the matter in litigation over EpiPen, the challenge to these contracts fails as a matter of law because the Complaint does not allege that Teva "coerced customers or engaged in any other exclusionary conduct beyond simply offering PBMs a better price." *See* Mylan MTD, at 41, No. 20-cv-827, ECF No. 92 (D. Minn. Aug. 21, 2020).[16]

As to the Conditional Rebates, the Complaint alleges that Teva's rebates "spanned at least two products," Compl. ¶ 165, presumably referring to Copaxone 20 mg and 40 mg, *see id.* ¶ 17. But this vague allegation is insufficient to make price anything less than the "predominant mechanism of exclusion" underlying Mylan's theory. Bundling is not a mode of exclusion when rivals can compete with offerings across the product line. *See, e.g.*, *Shire US, Inc. v. Allergan Inc.*, 375 F. Supp. 3d 538, 557 (D.N.J. 2019) (dismissing antitrust claim premised on an alleged bundled rebate where the complaint did not allege that the defendant maintained an incontestable monopoly over secondary products in the bundle);

[16] The allegation that Teva executives did not "disclose" its contracting strategy to Teva's sales staff, Compl. ¶ 169, has no conceivable relevance to whether Teva's agreements foreclosed competition.

Eisai Inc. v. Sanofi-Aventis U.S., LLC, 2014 WL 1343254, at *27-28 (D.N.J. Mar. 28, 2014) (applying the price-cost test to rebates for formulary access after rejecting an argument premised on incontestable demand). The Complaint does not allege that Teva's conditional rebates extended to products that Mylan is unable to offer. Nor could it have, since Mylan markets both 20 mg and 40 mg versions of generic GA. Compl. ¶ 80. Because Mylan was perfectly capable of offering its own rebates to PBMs on 20 mg and 40 mg GA, Teva's alleged bundling was not exclusionary as a matter of law.

b. The Complaint Does Not Plausibly Allege That Teva's Contracts Foreclosed A Substantial Share Of The Market Or Otherwise Blocked Competition On The Merits.

Even if the Court were to evaluate Teva's Conditional Rebates and Specialty Pharmacy Agreements under the default rule of reason, rather than under the price-cost test, Mylan still has failed to plead a plausible Section 2 claim. "[B]undled rebates" and "exclusive dealing contracts" are often "procompetitive," *Shire US, Inc.*, 375 F. Supp. 3d at 557, and "can offer consumers … economic benefits," though harming individual competitors, *Eisai, Inc.*, 821 F.3d at 403. Accordingly, a plaintiff must plausibly allege that the arrangement "will foreclose competition in such a substantial share of the relevant market so as to adversely affect competition." *ZF Meritor, LLC*, 696 F.3d at 271. To evaluate market foreclosure, courts consider the duration of the contractual arrangements and whether they are

terminable at-will. *Id.* at 271-72. "[I]f customers are free to switch to a different product in the marketplace but choose not to do so, competition has not been thwarted—even if a competitor remains unable to increase its market share." *Eisai, Inc.*, 821 F.3d at 403.

The Complaint fails this basic requirement. To begin, Mylan does not allege any factual basis from which to infer that Teva's agreements cover a substantial percentage of the market. The Complaint vaguely alleges that Teva entered rebate deals "with key PBMs," but it does not identify any such PBMs or their market share. Compl. ¶¶ 106, 165, 220. As for the Specialty Pharmacy Agreements, the Complaint alleges only that Teva entered an agreement with a ***single*** "specialty pharmacy owned by one of the largest PBMs," and then speculates about the existence of other "similar arrangements." *Id.* ¶ 166. That falls far short of plausibly alleging substantial market foreclosure.

The Complaint also lacks any allegations about the duration of Teva's alleged agreements with PBMs and specialty pharmacies or whether they were terminable. That omission is critical, because "short-term agreements … present little threat to competition." *ZF Meritor, LLC*, 696 F.3d at 286. Indeed, "[e]ven an exclusive dealing contract covering a dominant share of a relevant market need have no adverse consequences if the contract is let out for frequent rebidding." XI Phillip E. Areeda & Herbert Hovenkamp, *Antitrust Law* ¶ 1802g2 (4th ed. 2018);

see id. ¶ 1807b1 ("Discounts conditioned on exclusivity in relatively short-term contracts are rarely problematic."). As Mylan explained in *EpiPen*, "[s]hort-term and easily terminable agreements … are good for consumers." Mylan MSJ, at 64, No. 2:17-md-2785, ECF No. 1673-1 (D. Kan. June 28, 2019). Courts have thus repeatedly held that such agreements are non-actionable because they "don't produce significant exclusionary effects." *EpiPen*, 507 F. Supp. 3d at 1345 (collecting decisions) (quotation marks omitted).

The Complaint's failure to allege that Teva's agreements lock customers into long-term arrangements presumably is no oversight. Mylan well knows that rebate contracts with PBMs and other payors typically are "short in duration and easily terminable." *EpiPen*, 507 F. Supp. 3d at 1354 ("It's also undisputed that payors renegotiated contracts with … drug suppliers regularly, typically on an annual basis"). In *EpiPen*, Mylan successfully argued that its rebate contracts did not result in market foreclosure because "[p]ayors regularly invoked the contracts' termination provisions, and they frequently renegotiated their rebate percentages to secure better pricing from drug manufacturers in exchange for better formulary positions." *Id.*; *see id.* at 1344 (noting that payors invoked termination provisions "annually, and sometimes, even more frequently"). Mylan has not alleged that the market conditions are different here, which supports dismissal. *See Shire USA, Inc.*, 375 F. Supp. 3d at 558 (dismissing claims challenging agreements with

bundled discounts and exclusivity terms where the contracts were "for one year" and were "open for competitive bidding on an annual basis").

Finally, the Complaint does not plausibly allege that PBMs—which Mylan has described as "among the most powerful actors in the U.S. healthcare system," Mylan MSJ, at 2-3, No. 2:17-md-2785, ECF No. 1673-1 (D. Kan. June 28, 2019)—were coerced to enter into agreements with Teva. As discussed, pp. 43-47, *supra*, the Complaint's allegations boil down to price competition: Teva allegedly induced certain PBMs to privilege Copaxone over Mylan's generic product at the formulary or pharmacy levels with attractive rebates. But as Mylan successfully argued in *EpiPen*, "'[t]here is nothing wrong with' this kind of market conduct" because "it's not coercion for a payor to agree to accept a lower price." 507 F. Supp. 3d at 1347, 1349.

The Complaint nonetheless tries to insinuate coercion by repeatedly describing Teva's conditional rebate offers as "all-or-nothing." Compl. ¶¶ 17, 106, 165, 220, 238. In other words, Mylan contends that PBMs allegedly were coerced into accepting exclusivity arrangements with Teva that they did not want, because Teva would not do business with them on any other terms. But the Complaint's own factual allegations contradict this characterization: the Complaint excerpts a Teva document explaining that it had a "range" of contractual arrangements with PBMs, including agreements "allowing access to COPAXONE 40mg alongside

generic." *Id.* ¶ 163. The Court must discard conclusory labels that are undercut by the Complaint's own factual allegations. *See LLM Bar Exam, LLC v. BarBri, Inc.*, 271 F. Supp. 3d 547, 584 (S.D.N.Y. 2017). Those allegations show that, far from coercing customers into exclusivity, Teva offered customers a range of terms from which they could choose, and that conduct is not anticompetitive.

c. The Complaint Does Not Plausibly Allege Teva's PBM Agreements Caused Antitrust Injury.

The Complaint also fails to allege that the Conditional Rebates and Specialty Pharmacy Agreements caused Mylan to suffer antitrust injury—*i.e.*, harm of the type the antitrust laws were intended to prevent, "which flows from that which makes defendant's acts unlawful." *Race Tires Am., Inc. v. Hoosier Racing Tire Corp.*, 614 F.3d 57, 75 (3d Cir. 2010) (quotation marks omitted). To meet that standard, the plaintiff must plausibly allege that the defendant's anticompetitive conduct increased prices for consumers, reduced output, or negatively impacted product quality, and that the plaintiff's alleged harm results from these aspects of the defendants' conduct. *See Mathews v. Lancaster Gen. Hosp.*, 87 F.3d 624, 641 (3d Cir. 1996). The mere "loss of sales due to price competition is not an antitrust injury." *Eisai, Inc.*, 2014 WL 1343254, at *31; *accord Concord Boat Corp. v. Brunswick Corp.*, 207 F.3d 1039, 1061 (8th Cir. 2000) ("In the absence of predatory prices, any losses caused by pricing cannot be said to stem from an anticompetitive aspect of the defendant's conduct."). Moreover, "the Third Circuit

has found that exclusive contracts produce no antitrust injury when a competitor 'had the clear opportunity to compete.'" *EpiPen*, 507 F. Supp. 3d at 1366 (quoting *Race Tires Am.*, 614 F.3d at 84).

Here, Mylan does not allege that Teva's PBM contracts decreased output or affected product quality. The Complaint does include conclusory allegations that Teva charged "supracompetitive prices" for Copaxone, *e.g.*, Compl. ¶¶ 22, 109, 163, 185, but it also alleges that prices ***"decrease[d]"*** substantially "after generic entry for the 40mg dosage began in late 2017," *id.* ¶ 218 (emphasis added). Because the Complaint does not allege that Teva substantially increased prices ***after*** it entered the challenged agreements, those agreements could not have caused Mylan to suffer an antitrust injury.

Nor does the Complaint plausibly allege that Mylan was unable to compete with Teva for contracts. As discussed, pp. 46-47, *supra*, because Mylan markets both 20 mg and 40 mg product strengths, Teva derived no advantage against Mylan from an alleged two-product "bundle"—Mylan could have matched Teva's terms. The Complaint does allege that Mylan "attempt[ed] to compete directly on prices by reducing the list price of generic GA 40mg by 60% in July 2018," and that this "failed to result in the degree of generic conversion normally expected in a competitive market." Compl. ¶ 224. But this allegation, too, falls short. The Complaint does not explain the significance of a "60%" price reduction; for

example, it does not allege that Mylan would have stopped earning a profit if it had lowered prices further. *Cf. NicSand, Inc. v. 3M Co.*, 507 F.3d 442, 452 (6th Cir. 2007) (en banc) (explaining that a company has no right under the antitrust laws to preserve its desired profit margin). Nor does the Complaint allege facts to suggest that PBMs and other payors were unable to shift to Mylan's product following the alleged 60% price decrease if they had found Mylan's terms more attractive than Teva's rebates. Ultimately, the Complaint simply ***concludes*** that Mylan was unable to compete, Compl. ¶ 17, but such unadorned "conclusions … are not entitled to the assumption of truth," *Ashcroft v. Iqbal*, 556 U.S. 662, 679 (2009).

At bottom, Mylan appears to allege that it was injured simply by being forced to compete with Teva at all. Mylan repeatedly complains that Teva's contractual arrangements with PBMs "subvert[ed] automatic substitution laws." Compl. ¶¶ 105 n.8, 166, 220.[17] Mylan's apparent view is that a brand manufacturer should sit back and accept a loss of sales upon generic entry, rather than find ways to compete. But nothing in any state drug-selection law, much less the Sherman Act, forecloses a brand manufacturer from trying to preserve market

[17] Mylan insinuates that Teva's contracting strategy led pharmacies to fill prescriptions with Copaxone that had been earmarked for Mylan's product, Compl. ¶ 17, but the Complaint does not allege any such prescriptions designated Mylan's product by name or specified that they should only be filled with a generic product. Rather, Mylan's grievance appears to be that Teva offered prices that induced some specialty pharmacies to fill general GA prescriptions with Copaxone (which is itself GA) rather than defaulting to one of the available generic options.

share after generic entry by offering aggressive rebates to PBMs or pharmacies to make the brand product more attractive than generic alternatives. Thus, even if Teva's competitive efforts led to less "generic conversion" than Mylan "expected," *id.* ¶ 195, Mylan's dashed expectations do not amount to an antitrust injury.

3. Mylan's "Kickback" Allegations Do Not Support A Section 2 Claim.

Mylan next tries to buttress its Sherman Act claim with allegations that Teva violated an entirely different law—the Anti-Kickback Statute ("AKS"), 42 U.S.C. § 1320a-7b(b)—by allegedly making charitable contributions to foundations that pay patients' out-of-pocket costs for Copaxone. *See* Compl. ¶¶ 109, 170-75. To support this theory, Mylan relies on a pending Department of Justice lawsuit against Teva, *id.* ¶ 173, in which the DOJ has alleged that Teva improperly directed its donations "almost exclusively [to] Copaxone patients rather than … MS patients in general," *United States v. Teva Pharms. USA, Inc.*, __ F. Supp. 3d __, 2021 WL 4132592, at *2 (D. Mass. Sept. 9, 2012). These "kickback" allegations offer no support for Mylan's Section 2 claim.

To begin, Mylan's theory that Teva "used" its charitable contributions to block generic conversion, Compl. ¶ 109, is inconsistent with the Complaint's own allegations. The Complaint alleges that Teva's donation program was in place "[f]or more than a decade," going back to 2008, *id.* ¶ 170—years before the FDA approved ***any*** generic versions of Copaxone, *id.* ¶¶ 75-76, 79. The Complaint

never alleges that Teva increased its charitable contributions in response to generic competition; in fact, it does not allege any "kickbacks" past 2018, even though Mylan started selling generic GA in late 2017. *Id.* ¶ 173.

More fundamentally, Mylan's theory fails because the alleged "kickbacks" are not anticompetitive. Stripped of pejorative labels, Mylan's contention is that Teva's contributions incentivized Medicare patients to select Copaxone by lowering their co-pays. *See* Compl. ¶¶ 170-71, 174. But competing on the basis of price "is the very essence of competition." *Phila. Taxi Ass'n, Inc.*, 886 F.3d at 340 (quotation marks omitted). Outside the Medicare context, co-pay coupon programs for brand products are commonplace. *See, e.g.*, *Am. Fed'n of State, Cnty. & Mun. Emps. Dist. Council 37 Health & Sec. Plan v. Bristol-Myers Squibb Co.*, 948 F. Supp. 2d 338, 343 (S.D.N.Y. 2013) (describing co-pay subsidy programs as a "cottage industry" and dismissing a challenge to a program). In fact, Mylan acknowledges that Teva made contributions to lower co-pays for MS patients with private insurance, *see* Compl. ¶¶ 109, 171, 175, but it never alleges that those efforts were anticompetitive—because they plainly were not. The antitrust analysis is not affected by adding the complex legal overlay of Medicare reimbursement rules to the equation. Teva disputes that its contributions to independent charities violated the AKS, but that question is irrelevant here. At worst, the Complaint's kickback allegations imply that Teva's donations

functioned like a coupon-subsidy program for Medicare patients because Teva was able to target its donations to help only Copaxone patients. But, as just discussed, a coupon-subsidy program is ***not*** anticompetitive.

Mylan cannot transform Teva's procompetitive conduct into an antitrust violation by invoking the AKS. It is well-established that "[e]ven unlawful conduct is of no concern to the antitrust laws unless it produces an anticompetitive effect." *Phila. Taxi Ass'n, Inc.*, 886 F.3d at 340 (quotation marks omitted). Thus, Mylan cannot conjure up an antitrust violation from allegations that Teva engaged in price competition by lowering the out-of-pocket costs for patients, on the theory that Teva's discounts allegedly violated another law. *See Wichita Clinic, P.A. v. Columbia/HCA Healthcare Corp.*, 45 F. Supp. 2d 1164, 1192-93 (D. Kan. 1999) (rejecting claim that a violation of the AKS would "constitute the sort of antitrust injury that would justify a claim under Section 2"). The Sherman Act was "never meant to be a panacea for all wrongs." *Sitkin Smelting & Ref. Co. v. FMC Corp.*, 575 F.2d 440, 447-48 (3d Cir. 1978) (quotation marks omitted).

In fact, far from supporting Mylan's Section 2 claim, the existence of a distinct regulatory regime policing government reimbursements and alleged "kickbacks" counsels strongly ***against*** extending the antitrust laws to punish patient discounts. Where a regulatory structure exists to "deter and remedy anticompetitive harm … the additional benefit to competition provided by antitrust

enforcement will tend to be small, and it will be less plausible that the antitrust laws contemplate such additional scrutiny." *Trinko, LLP*, 540 U.S. at 412-13. Here, the AKS provides "a comprehensive bifurcated civil and criminal scheme for addressing fraudulent and abusive payment practices in federal health care programs," and "complex, detailed regulations" have been promulgated to implement the statute's requirements. *PPD Enters., LLC v. Stryker Corp.*, 2017 WL 4950064, at *3 (S.D. Tex. Nov. 1, 2017) (quotation marks omitted). There is no reason to stretch antitrust law to cover an area subject to its own robust enforcement regime. Indeed, doing so would allow an end-around Congress's decision to give enforcement authority over potential AKS violations exclusively to the Attorney General. *See Allstate Ins. Co. v. Linea Latina De Accidentes, Inc.*, 781 F. Supp. 2d 837, 850 (D. Minn. 2011). Other courts have rightly rejected attempts by private plaintiffs to repurpose the Sherman Act to challenge alleged AKS violations.[18] This Court should follow suit.

Until this lawsuit, Mylan accepted all of the above reasoning. When faced with a Sherman Act claim premised on alleged violations of the AKS, Mylan urged dismissal because the "AKS was enacted to combat a specific type of conduct, separate and apart from the conduct contemplated by the Sherman Act," and thus

[18] *See, e.g.*, *Digene Corp. v. Third Wave Techs., Inc.*, 536 F. Supp. 2d 996, 1006 (W.D. Wis. 2008); *Action Ambulance Serv., Inc. v. Atlanticare Health Servs., Inc.*, 815 F. Supp. 33, 37-38 (D. Mass. 1993).

AKS violations are "insufficient to support a monopolization claim." Mylan MTD, at 44, No. 20-cv-827, ECF No. 92 (D. Minn. Aug. 21, 2020).[19] Teva agrees.[20]

4. Teva's 2020 Suit Against The FDA Is Immune From Antitrust Attack And Did Not Injure Mylan In Any Event.

Finally, the Complaint alleges that, after generic GA products had "gaine[d] some limited market share," Teva filed "baseless regulatory and court filings" asking the FDA to reclassify Copaxone as a biological product rather than a drug. Compl. ¶¶ 176-91. According to the Complaint, Teva's actions "were designed to completely eliminate generic competition to Copaxone" because if the FDA had "granted" the relief that Teva requested (or a court had ordered the FDA to do so), it "would have immediately eliminated automatic substitution." *Id.* ¶ 176. These allegations cannot support an antitrust claim, for two independent reasons.

First, Teva's request that the FDA reclassify Copaxone as a biological product and Teva's subsequent lawsuit are entitled to *Noerr-Pennington* immunity. As noted, a lawsuit or agency petition is not a sham if the filing party "intends to

[19] The Court there held that bribery allegations against Mylan could support a Section 2 claim on the pleadings, but the allegations there involved bribes to deny competitors the ability to access the market. *See In re EpiPen Direct Purchaser Litig.*, 2021 WL 147166, at *24 (D. Minn. Jan. 15, 2021) (collecting cases). No such allegations are present here.

[20] Even if violations of the AKS could support a Section 2 claim, Mylan cannot recover damages related to any donations made prior to June 2017, as such alleged conduct falls outside the four-year limitations period. *See Klehr v. A.O. Smith Corp.*, 521 U.S. 179, 189-90 (1997).

achieve" the allegedly anticompetitive goal "by actually succeeding." *Takeda*, 2021 WL 3144897, at *17. But the Complaint only claims that Teva tried to secure an advantage by persuading the FDA or a court to reclassify Copaxone. Compl. ¶¶ 176, 183. In other words, Mylan accuses Teva not of process abuse, but of merely seeking an ***outcome*** that Mylan labels anticompetitive. *Noerr-Pennington* immunity therefore applies. *See Campbell v. Pa. Sch. Bds. Ass'n*, 972 F.3d 213, 219 (3d Cir. 2020).[21]

Second, the Complaint does not plausibly allege that Teva's actions harmed competition. To the contrary, the Complaint alleges that "Teva's … anticompetitive effort … failed." Compl. ¶ 191. Instead, the Complaint merely alleges that Teva's actions "forced Mylan to intervene as a defendant and expend significant resources to defend against [Teva's] lawsuit." *Id.* But Mylan was not "forced" to intervene; it chose to enter the case rather than rely on government counsel to defend the FDA's decision, presumably because Mylan perceived some risk that Teva might win. Thus, any legal expenses Mylan incurred resulted from its own strategic decisions; they were not "inflicted" upon Mylan through Teva's "use of legal process." *PRE*, 508 U.S. at 65.

[21] Teva's arguments for reclassifying Copaxone also were not objectively baseless. Teva's claims were premised on a recent amendment to the statutory definition of "biological product" that neither the FDA nor any court had previously interpreted, Compl. ¶ 180, and which resulted in a 61-page published opinion and a recognition that the relevant statute was ambiguous, *Teva Pharms.*, 514 F. Supp. 3d at 85.

D. The Complaint's Allegations Regarding Foreign Regulatory Processes Are Legally Irrelevant And Should Be Stricken.

The Complaint also contains numerous allegations regarding purported anticompetitive actions by Teva outside the United States, including alleged activities in Europe, but it makes no effort to tie those allegations to a claim for relief. *See* Compl. ¶¶ 92-100. Thus, if any part of Mylan's Complaint survives this motion to dismiss, the Court should exercise its authority under Federal Rule of Civil Procedure 12(f) to strike Paragraphs 92-100.

Rule 12(f) authorizes this Court to "strike" from the Complaint "any … immaterial … matter." Fed. R. Civ. P. 12(f). Allegations are "immaterial" when they "ha[ve] no essential or important relationship to the claim for relief." *Spanish Sports Network, LLC v. Spanish Football Prods., LLC*, 2021 WL 2284260, at *4 (D.N.J. June 4, 2021) (quotation marks omitted). Allegations of anticompetitive conduct in Europe are unquestionably "immaterial" here, as the Complaint identifies "[t]he United States and its territories" as the relevant geographic market. Compl. ¶ 215. Moreover, the Sherman Act does not apply to conduct occurring outside the United States, except in narrow circumstances not alleged here. *See F. Hoffmann-La Roche Ltd. v. Empagran S.A.*, 542 U.S. 155, 162 (2004).

Teva would be prejudiced if Mylan were allowed to move forward with the Complaint's legally irrelevant allegations because it would "substantially complicate the discovery proceedings." *Sprint Sols., Inc. v. J&S Invs. of*

Delaware, Inc., 2016 WL 11646540, at *2 (D.N.J. Dec. 1, 2016) (quotation marks omitted). This concern is not speculative: Mylan ***already*** has asked for discovery related to alleged conduct in Europe. *See* ECF No. 25 at 3 (discussing Mylan's discovery request). The Court should cut off this fishing expedition before it starts.

II. The Complaint Fails To State A Lanham Act Claim.

Section 43(a)(1)(B) of the Lanham Act prohibits, in relevant part, "any … false or misleading description of fact, or false or misleading representation of fact, which … in commercial advertising or promotion, misrepresents the nature, characteristics, qualities, or geographic origin of … goods, services or commercial activities." 15 U.S.C. § 1125(a)(1)(B). Lanham Act "false advertising" claims are subject to a heightened pleading standard, which requires the plaintiff to provide "sufficiently detailed allegations regarding the nature of the alleged falsehoods to allow [the defendant] to make a proper defense." *Interlink Prods. Int'l, Inc. v. F&W Trading LLC*, 2016 WL 1260713, at *5 (D.N.J. Mar. 31, 2016) (quotation marks omitted).

To state a claim under the Lanham Act, a plaintiff must plausibly allege, among other things, that misrepresentations came in "commercial advertising or promotion." *See Groupe SEB USA, Inc. v. Euro-Pro Operating LLC*, 774 F.3d 192, 198 (3d Cir. 2014). To qualify as "commercial advertising or promotion," contested commercial statements must be "disseminated sufficiently to the relevant

purchasing public to constitute 'advertising or promotion' within that industry." *CHW Grp., Inc. v. Better Bus. Bureau of New Jersey, Inc.*, 2012 WL 426292, at *3 (D.N.J. Feb. 8, 2012). Courts have described "the touchstone" as whether "the contested representations are part of an organized campaign to penetrate the relevant market." *Fashion Boutique*, 314 F.3d at 57. Thus, allegations of "isolated disparaging statements" are insufficient. *Id.*; *see also Cronin v. Bergmann*, 2014 WL 5285930, at *3 (E.D. Pa. Oct. 16, 2014) (claim insufficient when based on "an unknown number of isolated statements made by Defendants" that were "not sufficiently disseminated to the public"); *Optimum Techs., Inc. v. Home Depot USA, Inc.*, 2005 WL 3307508, at *5 (N.D. Ga. Dec. 5, 2005) (similar).

The Complaint's allegations fall short of this standard, because Mylan relies on "unsupported conclusions and unwarranted inferences" that courts do not accept even on a motion to dismiss. *Mazo v. Way*, __ F. Supp. 3d __, 2021 WL 3260856, at *3 (D.N.J. July 30, 2021). The Complaint relies on just a handful of alleged statements, only three of which it directly "attribute[s]" to Teva. *See* Compl. ¶¶ 144, 149, 156. These isolated statements—the only ones put forward with anything like the requisite "detail," *Interlink Prods. Int'l, Inc.*, 2016 WL 1260713, at *5—are not equivalent to "an organized campaign" to disparage a product. *E.g.*, *Fashion Boutique*, 314 F.3d at 57-58 (court "easily conclude[d]" that "twenty-seven oral statements regarding plaintiff's products in a marketplace of thousands

of customers" did not qualify as commercial marketing or promotion); *Procter & Gamble Pharms., Inc. v. Hoffmann-LaRoche, Inc.*, 2006 WL 2588002, at *32 (S.D.N.Y. Sept. 6, 2006) (representations made on 561 calls (out of 25,000) was too "small" a fraction to be actionable as commercial advertising or promotion); *Auto-Chlor Sys. of Minn., Inc. v. JohnsonDiversey*, 328 F. Supp. 2d 980, 1019-20 (D. Minn. 2004) ("three statements by [sales] representatives to three customers in a marketplace of hundreds of customers" "clearly does not fall within the boundaries of commercial advertising or promotion").

Mylan seeks to bolster its threadbare allegations by relying on the resistance that it allegedly encountered to its product from some medical professionals. *See, e.g.*, Compl. ¶¶ 135, 143, 148, 153 (describing "belief[s]" and "understanding[s]" among some medical professionals, but without any attribution to specific Teva statements); *id.* ¶ 157 ("A doctor in Southern California argued with a Mylan representative that Mylan's generic GA product is materially different from Copaxone."). However, the Complaint's effort to blame Teva for these allegedly mistaken beliefs is conclusory and vague. *E.g.*, *id.* ¶¶ 138, 145, 150, 159.

Moreover, the Complaint makes an ***additional*** inferential leap by alleging that the mistaken beliefs of some medical providers "reflect[] a coordinated campaign by Teva to spread misinformation." Compl. ¶ 158; *see, e.g.*, *id.* ¶¶ 6, 13, 99, 219, 238. But the inferences of wrongdoing that Mylan draws from resistance

to its product do not clear the plausibility threshold. "Allegations that are merely consistent with a defendants' liability or show the mere possibility of misconduct are not enough," particularly when there is "an obvious alternative explanation." *Santiago v. Warminster Township*, 629 F.3d 121, 133 (3d Cir. 2010).

Here, there is an obvious alternative explanation to account for the negative feedback that Mylan received: some medical providers and patients were skeptical of switching to a new product after having used Copaxone successfully to treat MS. *See* p. 40, *supra*. It is undisputed that GA is exceptionally complex—far more so than an ordinary small-molecule drug. *See* pp. 8-9, *supra*. And because it is administered by injection, rather than chewed or swallowed, administration requires extensive patient support and training. *See* p. 8, *supra*; Compl. ¶ 151. It is thus unremarkable that some medical providers would have been skeptical about transitioning patients to a new generic product outside of Teva's established support structure, and that some patients would have expressed similar concern to their medical providers. Mylan should not be allowed to leverage that skepticism in order to turn allegations involving just a handful of alleged misstatements by Teva sales personnel into a Lanham Act claim.

III. Mylan's State Law Claims Should Be Dismissed.

Mylan also raises four claims under New Jersey law: tortious interference with prospective contractual relations or prospective economic benefit; unfair

competition; trade libel; and violation of the New Jersey Antitrust Act. *See* Compl. ¶¶ 262-97. If the Court dismisses Mylan's federal-law claims, particularly at this "early stage in the litigation," it should decline to exercise supplemental jurisdiction over the state-law claims. *See Strategic Env't Partners, LLC v. Bucco*, 184 F. Supp. 3d 108, 134 (D.N.J. 2016). Dismissing those claims now "will result in neither a waste of judicial resources nor prejudice to the parties," and will further avoid "[n]eedless decisions of state law" in federal court. *Mattern v. City of Sea Isle*, 131 F. Supp. 3d 305, 319-20 (D.N.J. 2015).

CONCLUSION

The Court should strike paragraphs 92-100 of the Complaint and dismiss the Complaint with prejudice.

Respectfully submitted,

s/ Liza M. Walsh

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